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**THE EFFECTS OF NI-TI HAND FILES, NI-TI ENGINE FILES, AND
K-FLEX FILES ON ROOT CANAL MORPHOLOGY**

by

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SECTION ONE: INTRODUCTION

A. STATEMENT OF THE PROBLEM:

It is well recognized that effective cleaning and shaping of the root canal system is crucial to success in endodontic therapy. The removal of pulp tissue, debris, and irritants is necessary for healing and the proper shaping of the canal is an important factor in achieving a dense, leak-resistant, three dimensional obturation of the canal space.

Numerous investigators have shown that current instrumentation techniques are inadequate in completely cleaning the canal due to the complex internal anatomy of the root canal system and inadequate instrument design. Significant alterations of the canal morphology can occur during the instrumentation of curved canals. The indiscriminate and aggressive cutting action of files and the tendency of unyielding larger size files to straighten out in the canals creates alterations that may be significant enough to produce a ledge or a perforation which are difficult to seal completely with conventional obturation materials. Various instrumentation techniques have been devised and minor changes in the design of the files have been accomplished in an attempt to reduce some of these problems. Mechanical instrumentation systems have also been developed to reduce time and fatigue in instrumentation. Despite these various modifications and improvements, instrumentation still remains a challenging, time-consuming, and problematic area in endodontics.

In the past, the majority of endodontic files and reamers were manufactured from either carbon steel or stainless steel. Large instruments manufactured from these metals have the property of decreased flexibility and the undesirable tendency of straightening curved root canals. Recently, hand and engine-driven endodontic files manufactured from nickel-titanium alloy have been introduced to the dental profession. Nickel-titanium alloy has the distinct advantage in that it is both stronger and more flexible than stainless steel and carbon steel. The manufacturer believes that these files will tend to follow the curvature of the canal more closely and cause less alteration in the anatomic shape of the canal. It is also believed that larger size nickel-titanium files can be used safely in curved canals and this would possibly result in more effective cleaning and shaping of the root canal system.

Scientific research examining the effects of nickel-titanium hand files and engine-driven files on root canal morphology is virtually non-existent. The instructions for clinical use of these files appear to be based solely on empirical data. The claims made by the manufactures of these instruments are therefore largely unsupported by published scientific research. Many questions arise concerning the safety, efficacy, and physical properties of these instruments and obviously, they can not all be answered in one study. This study will attempt to examine the effects of the nickel-titanium hand and engine-driven files on the root canal morphology of curved canals as compared to stainless steel K-flex files using a conventional instrumentation technique

B. SIGNIFICANCE OF THE PROBLEM:

Success in endodontic treatment is influenced by the practitioner's ability to safely and effectively clean and shape the root canal. When a new type of instrument is introduced to the profession, it should be thoroughly evaluated for safety and efficacy. Unfortunately, this is not always the case, and products can be marketed before any scientific research is completed. The idea of a nickel-titanium hand file is appealing especially if these files are found to be safer and more effective than stainless steel files. At the present time, practitioners should be cautious in the use of these instruments since the claims of the manufacturers are not well supported by scientific research.

The concept of an engine-driven endodontic file is not a new one, however, previous systems were found to be unsatisfactory. The introduction of nickel-titanium engine-driven files is both revolutionary and exciting. If these files are found to be safe and effective, they could revolutionize the practice of endodontics. This study will attempt to answer some important questions concerning the effects of these new instruments on root canal morphology. Hopefully, the information will aid the clinician in evaluating the usefulness and safety of these files.

C. NULL HYPOTHESIS:

No significant differences exist among K-files, nickel-titanium hand files, and nickel-titanium engine-driven files in the instrumentation of curved lower molar mesial root canals when comparing the following parameters: direction and extent of canal transportation, area of dentin removed, roundness of the canal, and the centering ability of the instruments.

D. ASSUMPTIONS:

1. Any significant differences in the dependent variables (direction and extent of canal transportation, area of dentin removed, roundness of the canal, and centering ability) will only be caused by differences in the instrument types.
2. Differences in the morphology of the teeth will not significantly affect the data.
3. The sample size will be large enough to permit meaningful interpretation of the data and the statistical significance level of 0.05 will be appropriate for this study.
4. The methodology used to measure the dependent variables will be able to detect differences among the instrument types, if they exist.
5. The Bramante technique (12) simulates clinical conditions adequately to allow for clinically relevant conclusions to be drawn.

E. LIMITATIONS

1. The root canals instrumented in this study will not be identical in size, shape, curvature, or length.
2. A blinded study will not be possible due to obvious differences among instrument types.
3. The operator has considerable experience in the use of hand files in instrumentation but virtually no experience in using engine driven files at the apex.
3. This study must be completed and the manuscript submitted for publication by 1 June 1993.

SECTION TWO: REVIEW OF THE LITERATURE

Many endodontists believe that canal preparation procedures are the most important segment of endodontic therapy (1). It is clear that effective cleaning and shaping of the root and the establishment of a leak resistant apical seal are important in promoting the healing of periradicular pathosis.

Endodontic instrumentation is challenging and sometimes problematic because of the unique, complex, and unpredictable internal anatomy of the root canal system. The fine curved roots found in the posterior teeth present particular difficulties for the clinician. Both Walton (2) and Mizrahi (3) have

shown that no instrumentation technique is totally effective in removing pulp tissue, debris, and canal irregularities. Weine (1) found that regardless of the type of enlarging instrument or technique used, undesirable characteristics were produced in all preparations. The lack of flexibility together with the tendency of files to straighten out in curved canals can cause undesirable sequella such as ledging, zipping, transportation, or perforation. The ability of an endodontic instrument to stay centered in the root canal and to produce a rounded preparation has been considered desirable for effective debridement and obturation. Schneider (4) found that straight canals were more readily prepared round than curved canals and Jungmann(5) demonstrated that neither filing nor reaming would predictably produce a round preparation in the apical segment of curved canals.

Recognizing the deficiencies in conventional instrumentation, numerous investigators (1,6,7,8) have proposed new techniques or slightly modified existing instruments in an attempt to reduce or eliminate these undesirable results. In 1989, Wildey and Senia (9) introduced a new type of root canal instrument and instrumentation technique because they believed that the design of conventional files and reamers was responsible for many of the problems encountered in instrumentation. Engine-driven instrumentation systems such as the Giromatic and the Canal Finder were developed to increase efficiency, decrease time, and reduce fatigue.

In the past, many instrumentation techniques were studied by evaluating the postinstrumented canals without comparison to the preinstrumented canal. In 1987, Bramante (12) introduced a technique which allowed for a direct comparison to be made between the preinstrumented and postinstrumented canal. Since that time, at least three studies (13-15) have demonstrated the usefulness of this technique. The parameters of canal roundness, area of dentin removed, direction and extent of transportation, and centering ability were found to be most helpful in evaluating the root canal morphology after instrumentation. The results of these studies using the Bramante technique(13-15) and other types of instrumentation studies (1,2, 3, 5, 16-20) have shown that there is no clear consensus establishing which instrumentation technique is best.

Endodontic instruments have traditionally been composed of either carbon steel or stainless steel (24). These metals possess high strength but become very stiff when manufactured into larger size

instruments. Recently, hand files and engine-driven files composed of nickel-titanium alloy were introduced. Civjan (10) was one of the first investigators to propose the use of ni-ti alloy in endodontics. In 1988, Walia et al (11) reported on the physical properties of the first ni-ti root canal files that were machined from orthodontic wire. The ni-ti files were found to have two to three times more elastic flexibility in bending and torsion, as well as superior resistance to torsional fracture as compared to stainless steel files. In theory, ni-ti files should follow curved canals with reduced tendency to straighten the canal resulting in less transportation, ledges, zips, and perforations. Unfortunately, little scientific evidence is available to support this hypothesis with most of the information on these files being provided by the manufacturer.

The concept of using an engine-driven file to prepare the apical region is not new. Previous studies of the Giromatic and Canal Finder systems revealed significant problems including premature canal blockage, loss of tactile sensation, and breakage (16-19). Campos and del Rio (13) found that the Canal Finder system removed more dentin and transported the root canal more in the cervical and apical sections as compared with circumferential filing using hand files. The system being examined in this study differs from previous engine driven instruments in that a special low-speed, high torque engine is being used with the specially designed nickel-titanium files.

There are numerous questions to be answered concerning these new ni-ti files including the nature of their physical properties and design. One of the most significant areas to be investigated is the effect of these instruments on canal shape as compared with an established instrumentation technique. The purpose of this study is to compare the root canal preparations produced by ni-ti hand files with ni-ti engine-driven files and K-flex files using a telescopic preparation suggested by Ingle (20).

SECTION THREE: METHODS AND MATERIALS

A. SAMPLE DESCRIPTION

Extracted human mandibular first and second molars with fully formed apices will be used. They will be stored in 10% formalin after extraction. Thirty-six mesial canals with separate apical foramina will be used in this study. The degree of canal curvature will be measured from the buccal and mesial radiographic views using the technique developed by Schneider (4).

B. RESEARCH DESIGN

The thirty-six mesial roots will be randomly divided into three groups. No separate control group is necessary in this study because in using the Bramante technique (12) each canal is its' own control. A digital image of the preinstrumented canal will be stored on optical disk prior to instrumentation and this image will be used in the comparison to postinstrumented canals. A blinding process is not possible since there are obvious differences among the instrument types.

C. OPERATIONAL DEFINITIONS

Independent variables: Instrument type: K-flex, Ni-ti K-type file, and Ni-Ti engine-driven file.

Dependent variables: Measurement of canal roundness, direction and extent of canal transportation, mean centering ratio and area of dentin removed. The total time of instrumentation will also be measured.

Experimental control: In the Bramante technique, an image of the canal is recorded prior to instrumentation and this serves as the control for each canal.

D. METHODS

1. Tooth preparation

The occlusal surfaces of the teeth will be flattened on a model trimmer to provide even reference points for instrumentation. The distal roots will be removed with a #557 bur in a high speed handpiece and an access preparation will be made into the pulp chamber. Canal length will be determined by

placing a #10 file into each canal until it is just visible at the apical foramen. Working length will be 0.5 mm short of this length. Radiographs will be made using the clinical and proximal orientation with the #10 file in place and canal curvature will be determined using the method described by Schneider (4).

Each mesial root will be scored with a shallow longitudinal groove along the mesiobuccal line angle for orientation. A drop of wax will be used to seal the two apical foramina to prevent blockage with resin. A wet cotton pellet will be placed in the chamber and the access opening will be closed with Cavit. A mark 2.0 mm from the apical foramina and another mark 1.0 mm apical to the point where the canal begins to deviate from a straight line will be made around the circumference of the root. The roots will be embedded in clear casting resin using a brass jig as a matrix, according to the technique described by Bramante (12). After the resin has set, the resin block will be trimmed and orientation grooves will be placed on two opposing faces of the resin. The resin blocks will be coated with Vaseline and one-half of the block will be placed in a plastic beaker filled with die stone. After the stone has set, the plaster locking jig will be indexed, coated with Vaseline and set in another plastic beaker filled with die stone to form the second half of the locking jig.

The stone locking jig will be separated and the resin block will be cut perpendicular to the root surface and slightly coronal to the circumferential lines previously scribed on the root using a 0.15 mm diamond wafering blade in an Isomet low speed saw (Buehler Ltd., Evanston, IL). After sectioning, the exact fit of the resin sections will be verified using the plaster locking jig. If any movement in the cut sections is found, the specimen will be discarded. Two orientation crosses will be inscribed in the root sections to aid in image analysis.

2. Image Acquisition

The CARE (Computer Aided Radiographic Evaluation) (21,22) software developed at the University of Texas Health Science Center at San Antonio will be used to acquire, digitize, and store the images of the preinstrumented apical and mid-root sections. These images will serve as the controls for each canal and provide the basis for later image comparison. The hardware required for the image acquisition and analysis is the following: Intel 80486 AT/bus personal computer with 4 megabytes of internal RAM memory, 80 Mb hard disk drive, 5.25 and 3.5 inch floppy disk drives, optical disk drive, super VGA

(1024X768) display adapter, non-interlaced high resolution monitor, serial mouse or trackball, and standard keyboard. Image capture will be performed by an Imaging Technologies, Inc. VFG 100 frame grabber, Dage/MTI CDR 72 CCD video camera, DO Industry model 6000 lens and a transmission light system. The images will be stored on an optical disk drive and a backup disk drive for future retrieval.

3. Canal Instrumentation

The canals will be randomly assigned to one of three experimental groups. Equal distribution of canal curvatures will be verified for each group. In group A, the canals will be instrumented with K-flex files (Kerr, Romulus) using the quarter-turn pull telescopic technique described by Ingle(2). All instruments will be precurved by using the buccal clinical view radiograph as a guide. After coronal enlargement of the canal orifice with a #2 Gates-Glidden bur, the canals will be enlarged to a size #30 file 0.5 mm short of canal length followed by a sequential 1.0 mm step-back to a #45 file. Images of these postinstrumented canals will be stored and compared to the images of the preinstrumented canals. Orientation jigs are not necessary since the same orientation of the sections will be verified by the computer software. The canals will then be instrumented up to a #45 file at working length followed by a 1.0 mm step-back to a #60. The images of these canals will be stored and compared to the preinstrumented canals.

Group B will be instrumented with nickel-titanium hand files (Mity File, JS Dental Manufacturing, Inc, Ridgefield, Connecticut) using the same technique as described for Group A.

Group C will be instrumented using the Sensomatic Handpiece (Advanced Endodontic Concepts, Inc, Chattanooga, TN) and nickel-titanium engine-driven files (NT, Co, Chattanooga, TN) following the instrumentation technique recommended by Dr. John T. McSpadden (23). The canals will first be instrumented using #10 nickel titanium hand files 0.5 mm short of canal length utilizing the quarter-turn pull technique. Engine instrumentation will begin with a #15 NT file in the 16:1 gear reduction handpiece at 300 RPMs. The files will be slowly advanced apically at approximately 0.5 mm per second into the canal. As soon as working length is reached, the file will be backed out and the next larger size file will be used in the same manner. The canals will be enlarged to a size #30 NT engine-driven file

0.5 mm short of canal length and the canal orifice will be enlarged with a #2 Gates Glidden using a conventional slow speed handpiece before creating the sequential 1.0 mm step-back preparation to a #45 NT engine-driven file. Images of these canals will be stored and compared to the preinstrumented canals. The canals then will be instrumented up to a #45 NT engine driven file at working length followed by a 1.0 mm step-back to size #60 file. The images of the canals will be recorded and compared with the preinstrumented canals.

Instruments will be used once in each canal. The pulp chambers of the canals will be flooded with irrigation (2.5% NaOCl) during instrumentation and the canals will be irrigated with 5.0 ml of irrigant after each file size. The instrumentation procedures will be timed with a stopwatch to evaluate the time effectiveness of each instrument. The stone locking jigs will be coated with rubber base adhesive during instrumentation to prevent loss of irrigant and a vise will be used to stabilize the locking jigs during manipulation.

4. Image Analysis

The CARE software program will be used to compare the preinstrumented canal images with the postinstrumented canal images using the computer hardware discussed previously. The extent of canal transportation will be determined by measuring the greatest distance between the periphery of the postinstrumented canal and the corresponding periphery of the preinstrumented canal which will be overlaid on it by the software. The direction of canal transportation will be recorded as buccal, lingual, mesial or distal. The area of dentin removed will be calculated by subtracting the area of the preinstrumented canal from the area of the postinstrumented canal. The centering ratio, or the ability of the instrument to remain centered in the original canal will be calculated using the formula $(X1-X2)/Y$ (14). X1 represents the maximum extent of canal movement in one direction, X2 is the movement in the opposite direction; Y is the largest diameter of the final canal preparation(15). Canal shape will be subjectively classified as round or irregular based on gross visual appearance.

E. STATISTICAL ANALYSIS

Dr. Cheng Yuan was consulted concerning the appropriate statistical analysis of the data and the appropriate sample size. He offered the following suggestions:

The data of length of transportation, area of dentin removed, and centering ratio of different canal instruments will be compared. The method of analysis of variance will be used to determine the statistical significance of the differences. Distribution of the data will also be examined and if the data appear to be not normally distributed, the Wilcoxon's rank sum test will be used.

The roundness of the canals attributed to different instruments will also be compared. Chi-square test and Fisher's exact probability test will be used for testing statistical significance.

The data of a previous study (Leseberg and Montgomery (15)) was reviewed to help determine the sample size of the proposed study. Twelve teeth were used for each of the three instruments in the Leseberg-Montgomery study. One tooth was lost in one group and the total of 35 canals was observed and reported. A statistical power analysis indicates the sample size of 12 was adequate with the exception of the apical section with #45 file where the difference between instruments tends to be minimal. On this basis, we propose a sample of 12 canals per instrument for this study. The results of the pilot study will be analyzed to confirm this sample size estimation.

F. TIMETABLE

October 7, 1992	Submit to Department Research Committee and IRB
October 15, 1992	Meet with Department Research Committee
December 18, 1992	All materials assembled, pilot study completed
February 15, 1993	All data collected
March 15, 1993	Statistical analysis, tables, figures completed
March 30, 1993	Initial submission of paper
June 30, 1993	Air Force deadline for paper

G. MATERIALS AND BUDGET

1. Materials

a. Extracted teeth	available
b. Model Trimmer	available
c. Casting Resin with hardener (1 can)	\$20.00
d. Die Stone	available
e. Brass jigs for fabrication of acrylic blocks	available
f. C-clamps for holding plaster jigs together	\$5.00
g. Isomet Saw with diamond wafering blade	available
h. Radiographic film (36 films) and Dental X-ray Unit (18)	available
i. Plastic containers for fabrication of plaster jigs (18)	available
j. K-flex files sizes 10 through 60 (12 files per size)	available
k. Mity Files sizes 10 through 60 (12 files per size)	available
l. NT Engine Files sizes 10 through 60 (12 files per size)	\$210.00 (approx.)
m. Gear reduction handpiece (Advanced Endodontic Concepts)	\$110.00 (approx)
n. Digitizing equipment and software	available
o. Optical disc drive for storage of digitized images	\$215.00 (approx.)
p. #2 Gates Glidden Burs (12)	\$15.00 (approx.)
q. #557 burs (12)	available
r. High and low speed handpieces	available
s. Cavit (4 tubes), cotton pellets	available
t. Ektachrome slide film and processing	\$50.00 (approx.)
u. beading wax to seal apices	available
v. NaOCl irrigant (2 gallons)	available
w. Stopwatch	available
x. 10% Formalin	available
y. Computing Resources/Statistical Analysis	\$200.00 (approx.)
z. Rubber base adhesive (2 bottles)	available

2. Budget

a. Total expense for materials	\$825.00
Air Force Funding	\$1000.00
Funds Available	\$ 175.00

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